JUN 1 3 2002 K021656

510(K) SUMMARY

I. GENERAL INFORMATION

A. Submitted By:

Nuclear Diagnostics AB
Söder Mälarstrand 13
S-118 20 Stockholm, SWEDEN

Tel: +46 (0) 8-190325
Fax: +46 (0) 8-184354

Contact Person: Jan Bertling
At address above

B. Device Trade Name: HERMES HDAQ Acquisition Station and HERMES Workstation, Ver. 3.4

Common Name: Accessory to a Nuclear Scanner

Classification Name: Emission Computed Tomography System

II. DEVICE DESCRIPTION

The base product design for the HERMES HDAQ Acquisition Station and HERMES Workstation, Ver. 3.4 is the same as the one for the HERMES HDAQ Acquisition Station and HERMES Workstation (K002782). The HERMES system consists of two components, a data acquisition station and a computer workstation. The HERMES HDAQ acquisition station and workstation are designed for use with commercially available gamma cameras. Software applications control acquisition, processing, display, analysis, and management of data and can be connected via network to other vendors' medical imaging workstations.

III. INTENDED USE

The HERMES HDAQ Acquisition Station is a system designed to acquire nuclear medicine image data using a compatible gamma camera system. The HERMES Workstation is a system designed to process, display, analyze, and manage nuclear medicine and other medical imaging data transferred from other workstations or HDAQ acquisition stations.

IV. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the modified device are the same as the original device. The proposed modification is the addition of six additional software applications as described in the 510(k) submission. These software applications operate as independent applications on the workstation and the acquisition station.

V. TESTING

Testing of the modified device followed Nuclear Diagnostic AB's normal procedures. A test plan was developed containing a description of relevant test procedures. Test results were documented, including what was tested, expected results, who performed the test, and which resources were used (i.e., automated test tools).

VI. CONCLUSIONS

In summary, Nuclear Diagnostics AB has demonstrated that the intended use for the HERMES HDAQ Acquisition Station and HERMES Workstation, Ver. 3.4 is the same as the original device. The technological characteristics have been described insufficient detail to demonstrate that they are the same as the original device. Therefore, this premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug, & Cosmetic Act and its amendments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2002

Nuclear Diagnostics AB
% Mr. Jim Howard
Bio-Reg Associates, Inc.
11800 Baltimore Avenue, Suite 105
BELTSVILLE MD 20705

Re: K021656
Trade/Device Name: HERMES HDAQ Acquisition Station and HERMES Workstation Ver. 3.4
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: May 17, 2002
Received: May 20, 2002

Dear Mr. Howard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K021656

Device Name: HERMES HDAQ Acquisition Station and HERMES Workstation, Ver. 3.4

Sponsor Name: Nuclear Diagnostics AB

Indications for Use:

The HERMES HDAQ Acquisition Station is a system designed to acquire nuclear medicine image data using a compatible gamma camera system. The HERMES Workstation is a system designed to process, display, analyze, and manage nuclear medicine and other medical imaging data transferred from other workstations or HDAQ acquisition stations.

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑
Over-The-Counter Use ☐

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021656